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(54) Prosthetic device positioning apparatus

(57) A heart valve positioning apparatus has a plurality of circumferentially

spaced legs 9, to which an artificial heart valve 8 can be releasably held by sutures 3. The legs depend from an internally threaded holder 10 formed for co-action with a rod 14 slidably positioned in a holding disc 12 which carries spring clips 19 about its circumferential edge for releasable coaction with the sutures utilized to secure the valve in place.

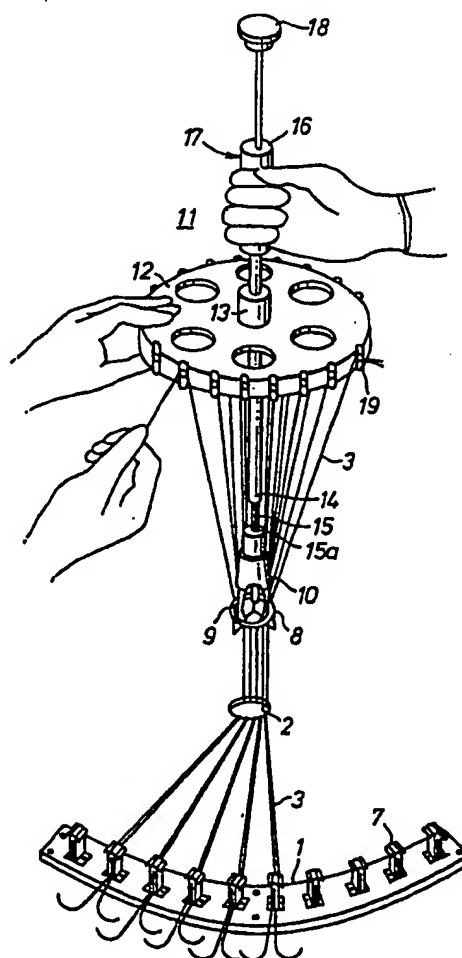
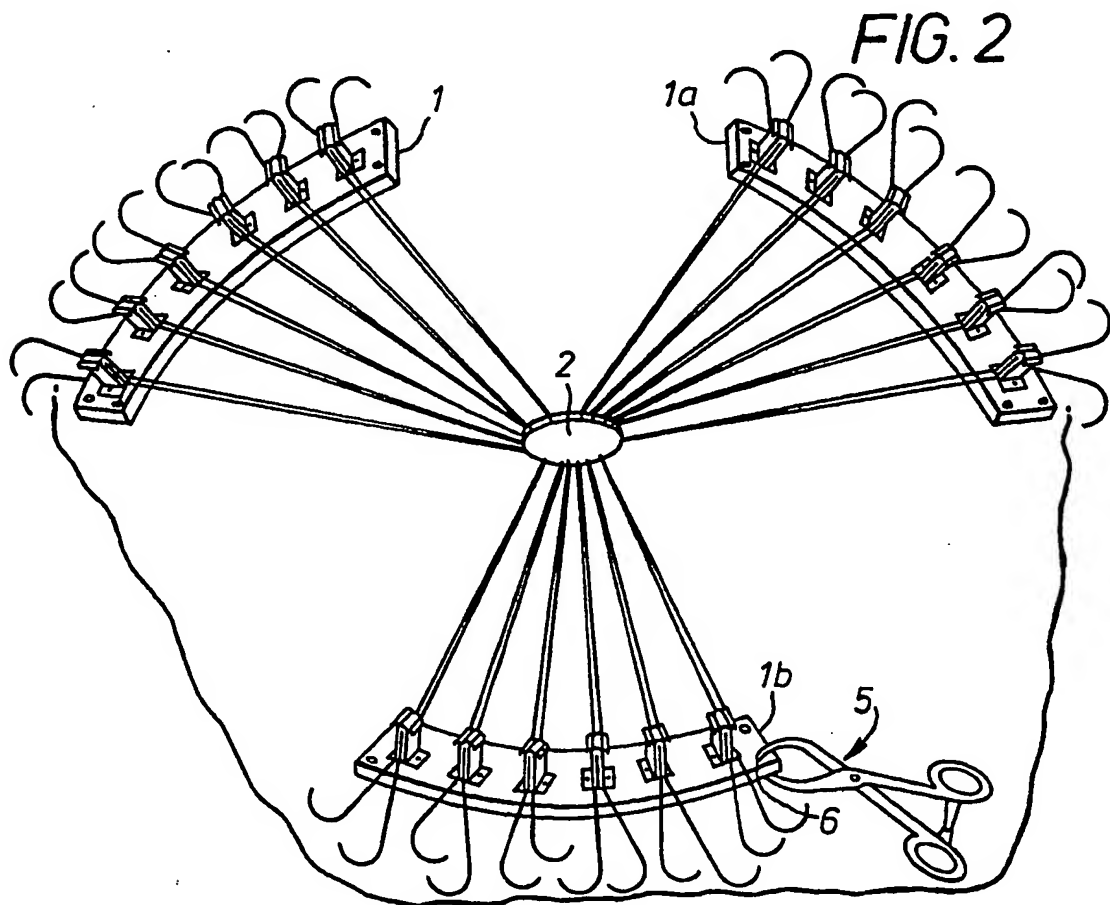
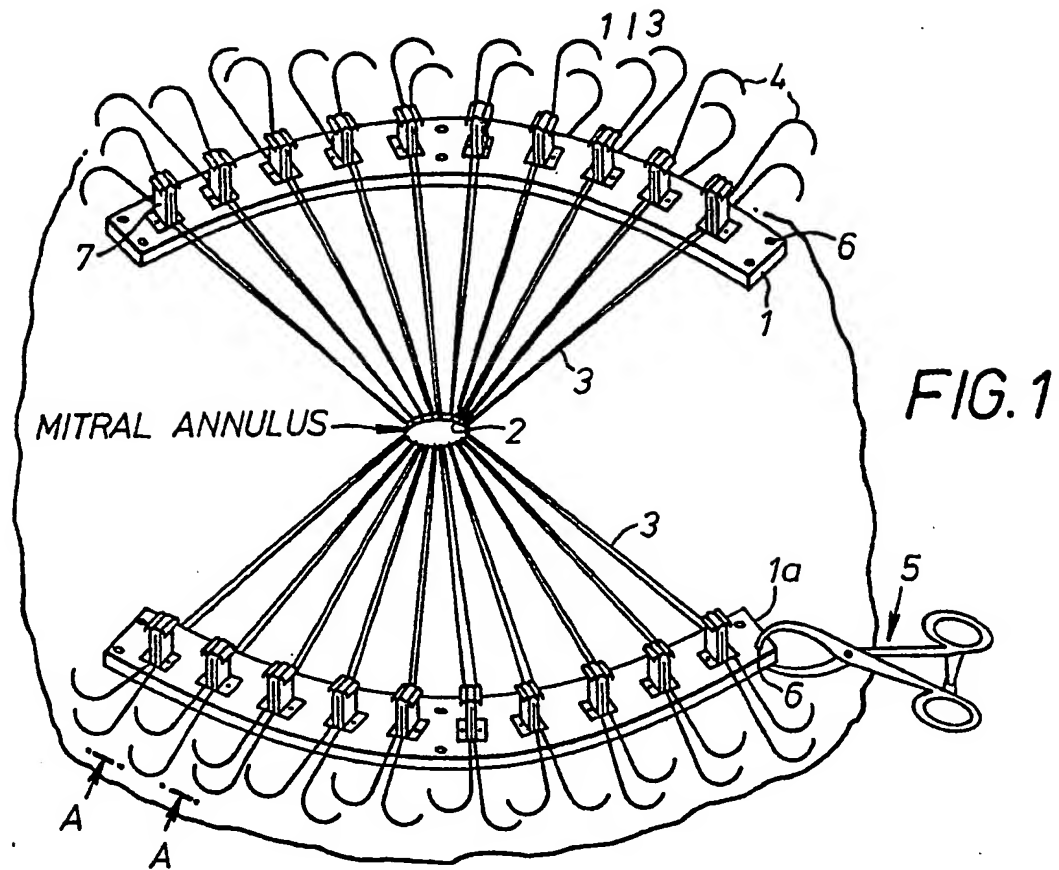


FIG. 4



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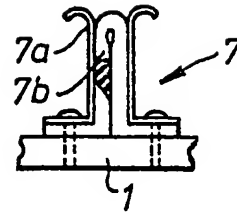


FIG. 3

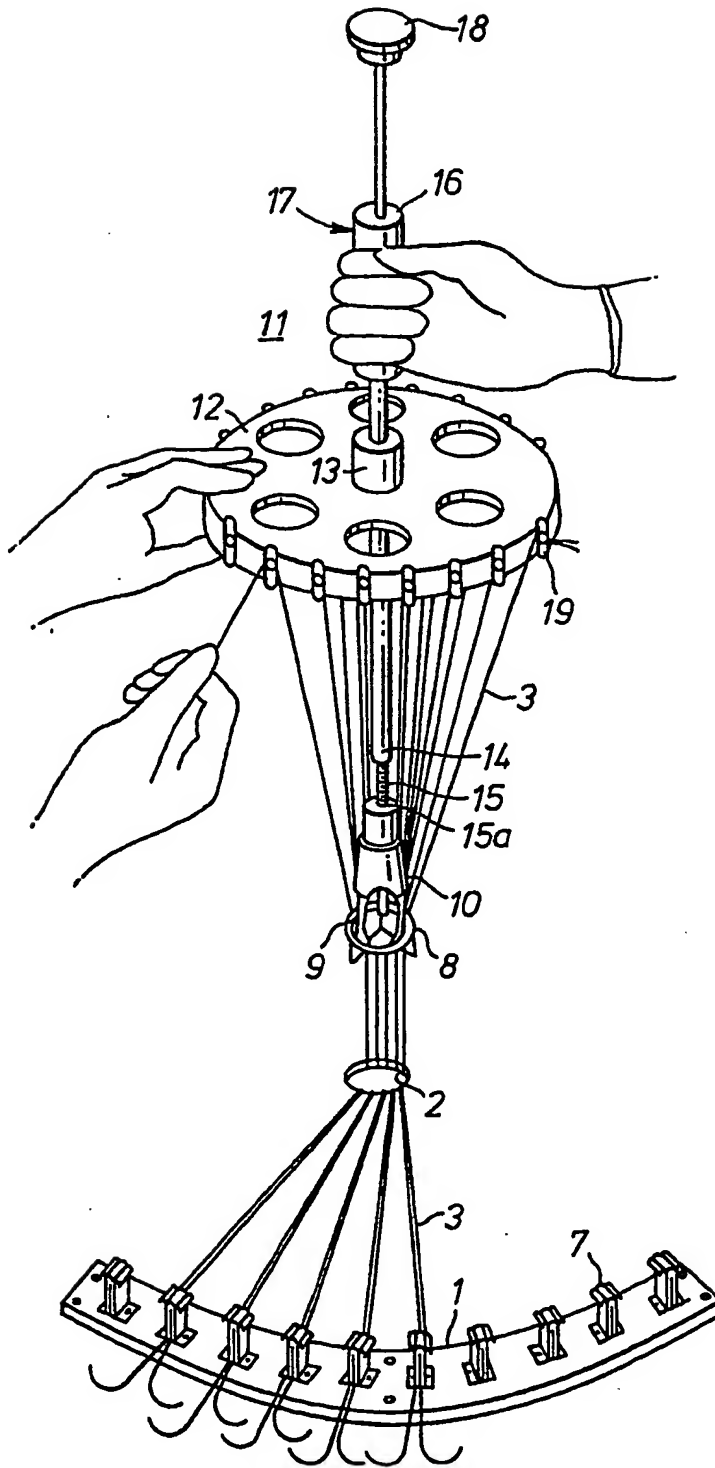


FIG. 4

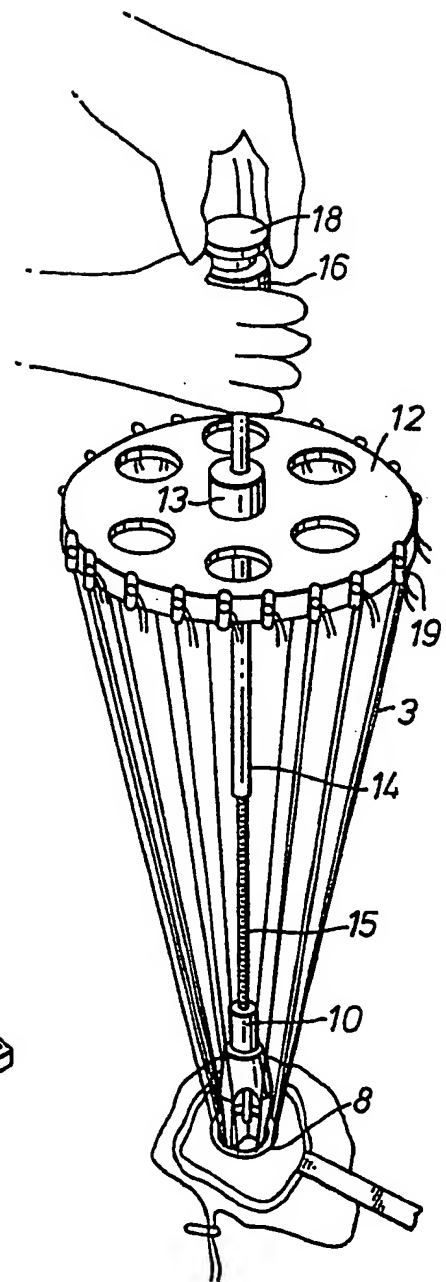
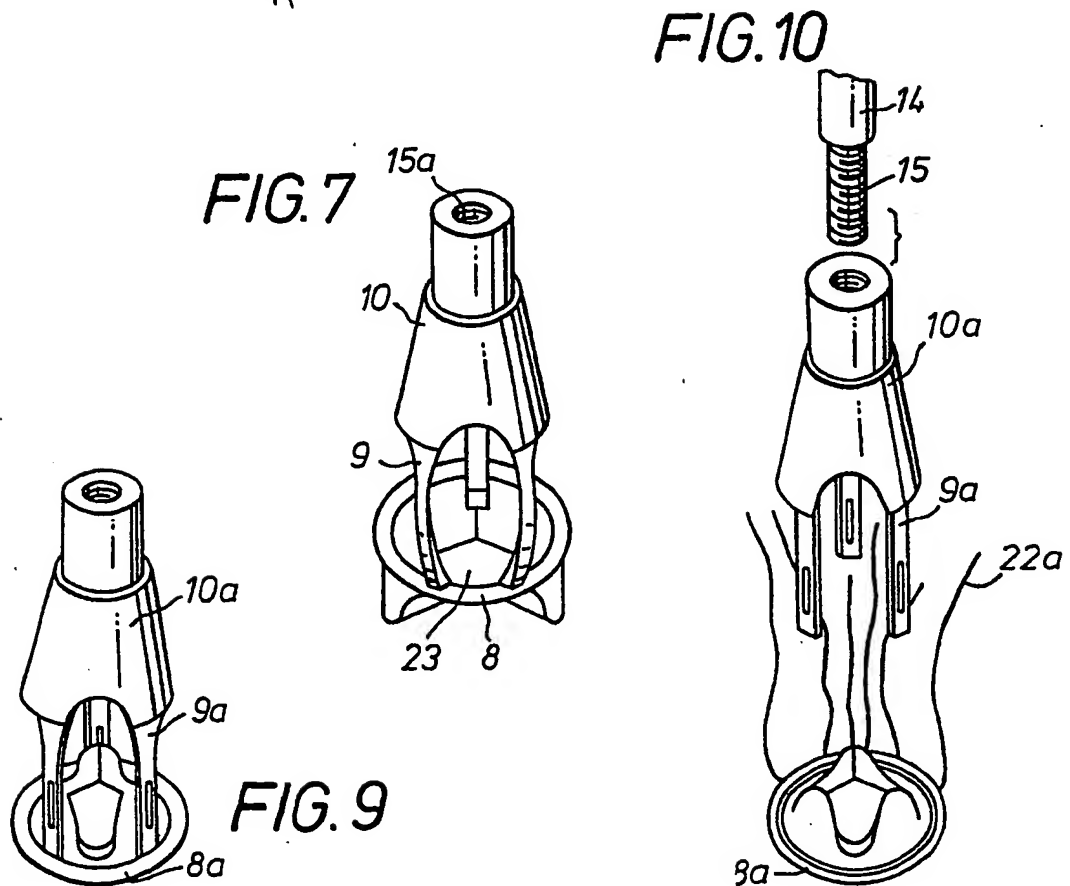
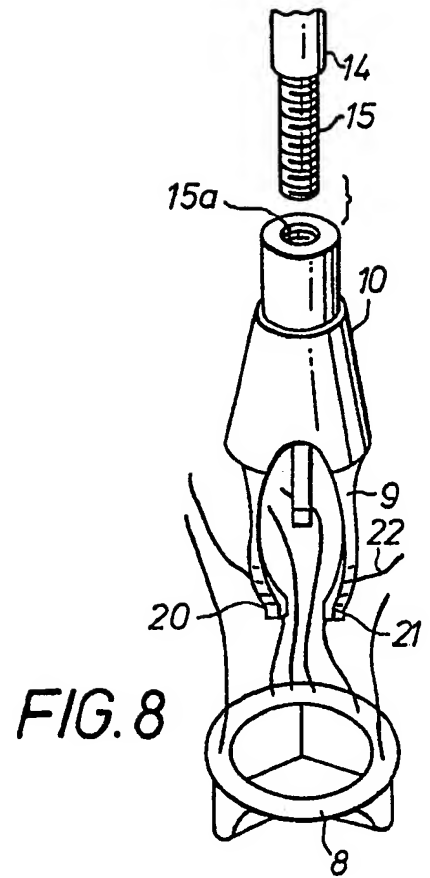
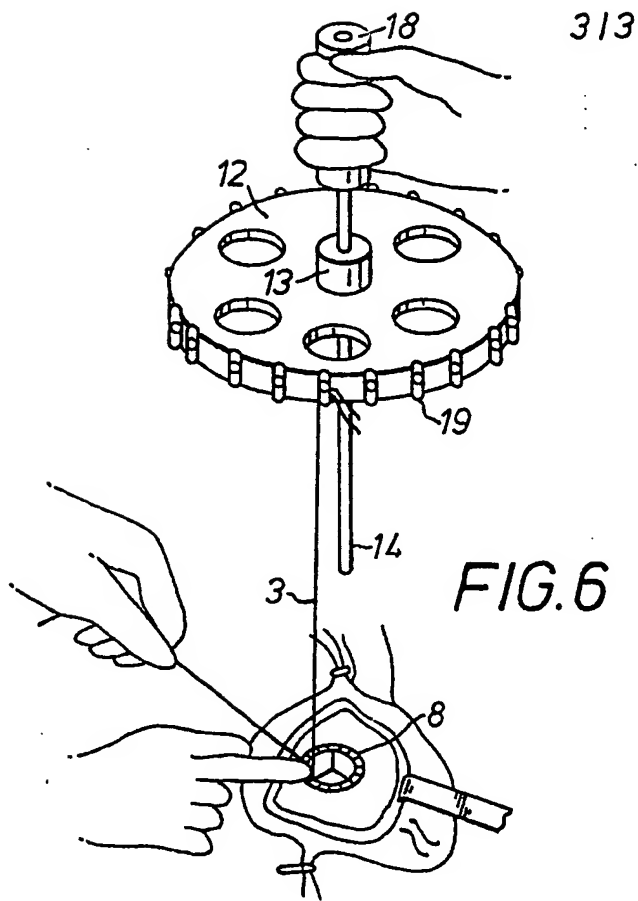


FIG. 5



## SPECIFICATION

## Prosthetic device positioning apparatus

- 5 This invention relates to surgical device utilized to facilitate speedy and orderly surgical procedures; and more particularly to a prosthetic device positioning apparatus.

- The time consumed in completing a serious medical operation, particularly operations which involve the exposure of the internal body cavity, is of extreme importance to the survival of the patient. Experience has shown that there is a direct relationship between the time span of the operation and its success.

- The above factors are particularly true in connection with such serious operations as open-heart surgery where there is not only the problem of exposure but which involves the use of artificial/mechanical means for maintaining the vital functions of the patient during the operation. In such operations, one of the more time-consuming steps involved in replacing a defective heart valve with an artificial valve is the attachment of the valve to the heart by means of multiple sutures, and this, of course, during the time when the patient is relying upon outside artificial means to sustain his or her life. During aortic valve replacement, the heart itself is cut off from the general circulation and is thereby denied the oxygen and nutrients it needs to maintain its integrity as a living tissue. During mitral valve replacement, some perfusion of the heart muscle is maintained, but not at an optimal level. Thus there are compelling advantages to keeping the heart muscle at risk for only the shortest possible time span.

- The proper positioning of the prosthetic device being implanted is quite essential if the surgical procedure is to be successful. Placement by hand is often difficult if not impossible due to the size of the device to be implanted, the restricted size of the area of implant and the conditions surrounding same. The use of complex holding devices facilitates the space problem, but often increases the time of the operation with attendant concerns.

An object of this invention therefore is to provide apparatus for use in surgical procedures for anastomoses and implantation of artificial heart valves.

- According to this invention therefore we provide a prosthetic device positioning apparatus; comprising

- a) a disc-shaped support having a central opening therethrough;
- b) a plurality of suture holders mounted about the periphery of said support;
- c) a rod slidably supported in said opening;
- d) a prosthetic device holder, formed to detachably hold and position a prosthetic device, mounted on one end of said rod such that sliding movement of said rod with respect to said support serves to position a prosthetic device for disposition on a patient when a prosthetic device is held by said apparatus and the apparatus is utilized during surgery.

In the drawings:

organizers suitable for use with a prosthetic device positioning apparatus;

Figure 2 is a plan view illustrating modified arrangement of the suture organizers;

- 70 Figure 3 is an enlarged view of an individual suture holder comprising a pair of spaced arms with resilient material therebetween;

- Figure 4 illustrates the use of a suture organizer as shown in Figure 1, together with a prosthetic device positioning apparatus in accordance with this invention;

- 75 Figures 5 and 6 illustrate sequential steps taking place during the implantation and suturing of an artificial valve following the initial step illustrated in Figure 4;

- 80 Figure 7 illustrates the combination of a mitral valve and valve holder for use with the apparatus shown in Figure 4;

- Figure 8 illustrates the disconnection between the valve holder and the artificial mitral valve of Figure 7; and

- Figures 9 and 10 are similar to Figures 7 and 8, showing an artificial aortic valve.

- Figure 1 shows individual suture organizers for use with a prosthetic device positioning apparatus in accordance with this invention, an embodiment of such apparatus being shown in Figure 4. The suture organizers shown and described here are the same as those described and claimed in Application No. 49628/78 from which this application has been divided out. The organizers are maintained by suitable and conventional means upon arcuately shaped supports or organizers 1 and 1a which will be placed upon the body of the patient (not shown) but on substantially opposite sides of the situs of the operation which in this case may be the mitral annulus 2. Multiple sutures 2 are threaded about the circumference of the annulus and for this purpose are preferably provided with needles 4. Except for the space immediately surrounding the situs of the operation, the body of the patient is generally covered with towelling or other suitable material and the frames 1 and 1a are sufficiently held in place by clamping to these towels through the use of a clamp 5 which may engage the frames through the use of openings 6. While frames 1 and 1a are shown as arcuate, other suitable configurations may be used.

- Instead of utilizing two organizers, as illustrated in Figure 1, it may for certain purposes be more convenient to utilize three or more such organizers as illustrated in Figure 2, at 1, 1a and 1b.

- The construction of the individual suture holders 7 (Figure 3) is of extreme importance in that they must firmly engage the sutures against lateral motion but must also permit the individual sutures to be quickly disengaged as by an upward motion therefrom. To that end, each individual suture holder is formed by a pair of spaced, preferably stainless steel or plastic, spring arms 7A between which is compressed a piece of soft rubber bent back upon itself, indicated at 7B. The combination of steel and soft rubber making up each individual suture holder is attached to frame 1 by suitable means such as bolts or rivets.

Figure 4 illustrates a prosthetic device positioning

use in the attachment of an artificial valve 8 to the annulus 2 of a diseased heart valve, and, as is shown, it is assumed that the diseased natural valve has already been removed; the patient at this point 5 being maintained by artificial means such as an external heart-lung machine. The basic sutures 3 are now in place and are being held by the individual suture holders 7 mounted on frame 1. The mitral valve 8, to be attached to the annulus 2, is temporarily 10 attached by sutures 3 to the arms 9 extending from a disposable plastic valve holder 10. Holder 10 may be made from Plexiglass (R.T.M.) or other suitable material, and it is contemplated that valve holder 10 and the valve 8 may be a preconnected 15 unit to form a disposable heart valve individually packaged and supplied to the surgeon. This unit is described and claimed in Application No. 49628/78. The combination of valve 8 and valve holder 10 is illustrated in more detail in Figure 7 to 10 and will be described in more detail hereinafter.

The application and attachment of artificial valve 8, to the annulus 2 of the diseased valve is preferably effected through the positioning apparatus 11 which 25 comprises a plastic disc 12 provided with an integral hub 13 through which may be slidably moved, a rod 14 preferably of stainless steel and provided with an externally threaded projection 15 engaging an internally threaded opening 15a in the top of disposable valve holder 10. Spaced above and integral with hub 13 is a hand grip 16 having a threaded opening into which a set screw 17 is threaded. The upper end of rod 14 is provided with a knob 18.

A plurality of spring clips 19 are attached about the 35 outer periphery of the disc 12 for holding sutures 3 in a manner hereinafter described.

Disposable valve holder 10 and its attached mitral valve 8 are illustrated in more detail in Figures 7 and 8, from which it will be seen that legs 9 extending 40 from valve holder 10 have cut-out portions 20 engaging the inner periphery of valve 8, legs 9 additionally being formed with openings 21 by means of which the valve 8 and valve holder 10 are joined together by sutures 22. Thus the initial unitary 45 structure comprises a valve holder 10 and valve 8 to be later disconnected as more clearly illustrated in Figure 8. Valve 8 is provided with the usual valve cusps 23 which may be made of suitable material and in the present form may actually be the valve 50 cusps removed from an animal such, for example, as a pig.

Figures 9 and 10 are similar to Figures 7 and 8 but illustrate the combination of a disposable valve holder 10a with an aortic valve 8a. In this form legs 55 9a of valve holder 10a may be straight and form a unit with valve 8a by attachment with sutures 22a.

The manner in which the apparatus described above is utilized in an actual operation will now be described in more detail with particular reference to 60 Figures 4, 5 and 6.

As shown in Figure 4, disc 12 supporting unitary valve and valve holder 8 and 10 is being held directly above mitral annulus 2, some of the sutures 3 remaining in holder 10 while others have already 65 been threaded through valve 8 and are supported on

disc 12 by the spring clips 19. In Figure 5, the valve is shown in place, having been pushed downwardly by rod 14 and sutures 3 attach valve 8 to annulus 2 and are all retained on clips 19 of disc 12. By loosening 70 set screw 17 and rotating knob 18, threaded extension 15 of rod 14 is removed from the top of valve 8 and disposable valve holder 10 is discarded, leaving valve 8 in place. As shown in Figure 6, the operation is substantially over, all sutures 3 but one having 75 been tied and valve 8 is firmly in place, having been attached to the heart and more specifically to annulus 2.

Obviously the same procedure is used in replacing the aortic valve except that in this case valve 8a and disposable holder 10 are utilized.

With respect to the disposable prosthetic device holder and the apparatus described and illustrated for performing the operation, variations in specific details are contemplated. For example, the number 85 of legs projecting from the body of the holder may be varied and differently positioned depending upon the shape of the prosthetic device, i.e., as for a semilunar valve.

From the above description it will thus be seen 90 that prosthetic device positioning apparatus have been shown with attendant surgical procedures; all of which are simple, efficient and most important serve to reduce the time required for surgery in operations where time is a critical factor.

## 95 CLAIMS

1. A prosthetic device positioning apparatus; comprising:
  - 100 a) a disc-shaped support having a central opening therethrough;
  - b) a plurality of suture holders mounted about the periphery of said support;
  - c) a rod slidably supported in said opening-
  - 105 d) a prosthetic device holder, formed to detachably hold and position a prosthetic device, mounted on one end of said rod such that sliding movement of said rod with respect to said support serves to position a prosthetic device for disposition on a patient when a prosthetic device is held by said apparatus and the apparatus is utilized during surgery.
2. Apparatus as claimed in Claim 1, wherein said suture holders are in the form of spring clips disposed about the periphery of said disc.
3. Apparatus as claimed in Claim 1 or Claim 2, wherein said prosthetic device holder includes a plurality of legs extending downwardly and formed to detachably hold a prosthetic device.
- 120 4. Apparatus as claimed in Claim 4, including a prosthetic device in the form of a heart valve detachably held by said legs.
5. Apparatus as claimed in any one of Claims 1 to 4, wherein said end of said rod is provided with a threaded extension, and said holder is threaded on said extension, whereby said holder may be removed from the end of said rod.
- 125 6. Apparatus as claimed in any one of Claims 1 to 5, wherein said disc is provided with an integral handle portion concentric with said central opening,
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a set screw extends through said handle portions abutting at its inner end against said slidable rod, and a knob is disposed at the end of said rod opposite the device holder.

- 5 7. Apparatus as claimed in any one of Claims 1 to 6, wherein at least one organizer for multiple sutures is formed to be placed for coaction with said apparatus during an operation in such a manner that sutures utilized during the operation may extend  
10 from said suture organizer through the patient and onto said suture holders mounted about said support.

8. A prosthetic device positioning apparatus substantially as described herein with reference to  
15 Figures 4 to 10.

New claims or amendments to claims filed on 30th November 1981

Superseded claims:- claims 1, 2, 4 and 7

- 20 New or amended claims:- claims 1, 2, 4 and 7

1. A prosthetic device positioning apparatus; comprising:

- a) a disc-shaped support having a central opening therethrough;  
25 b) a plurality of individual suture retainers mounted about the periphery of said support;  
c) a rod slidably supported in said opening;  
d) a prosthetic device holder, formed to detachably hold and position a prosthetic device, mounted  
30 on one end of said rod such that sliding movement of said rod with respect to said support serves to position a prosthetic device for disposition on a patient when a prosthetic device is held by said  
35 apparatus and the apparatus is utilized during surgery.

2. Apparatus as claimed in Claim 1, wherein said suture retainers are in the form of a plurality of individual and spaced apart spring clips disposed  
40 about the periphery of said disc.

4. Apparatus as claimed in Claim 3, including a prosthetic device in the form of a heart valve detachably held by said legs.

7. Apparatus as claimed in any one of Claims 1 to 6, wherein at least one organizer for multiple sutures  
45 is mounted in juxtaposition to said apparatus during an operation in such a manner that sutures utilized during the operation may extend from said suture organizer through the patient and onto said suture  
50 retainer mounted about said support.

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